# PRESS RELEASE

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## Emapalumab submission in China for primary HLH

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) today announced that a Marketing Authorization Application for emapalumab has been accepted for review in China. The targeted indication is for treatment of adult and paediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

"Today's announcement marks an important step for those affected by primary HLH, as currently there are no approved treatments available in China to meet the vast unmet medical need for this life threatening condition," said Ravi Rao, Head of Research & Development and Chief Medical Officer at Sobi.

**About primary HLH**
Primary HLH is a rare syndrome that typically presents in infancy but can also be seen in adults and is associated with high morbidity and mortality. In spite of some treatment advances, there continues to be a very high unmet medical need in particular in patients that have failed conventional therapy as there are no approved treatment options outside the US. In the US, emapalumab is the first therapy approved by the US Food & Drug Administration (FDA) for primary HLH. Over 100 patients have been treated in the US and the benefit/risk profile continues to be favourable.

**About emapalumab**
Emapalumab is a monoclonal antibody that binds to and neutralises interferon gamma (IFNγ). In the US, emapalumab is indicated for the treatment of adult and paediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. Primary HLH is a rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated. The FDA approval is based on data from the phase 2/3 studies (NCT01818492 and NCT02069899). Emapalumab is indicated for administration through intravenous infusion over one hour twice per week until haematopoietic stem cell transplantation (HSCT). For more information please see www.gamifant.com including the full US Prescribing Information. In September 2020, emapalumab received Orphan Drug Designation (ODD) by the FDA for prevention of graft failure following haematopoietic stem cell transplantation.

**About Sobi™**
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenues amounted to SEK 14.2 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

**For more information please contact**
Paula Treutiger, Head of Communication & Investor Relations
+ 46 733 666 599
paula.treutiger@sobi.com